IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED SATES OF AMERICA *ex rel.* AMY BERGMAN, et al.	:	**CIVIL ACTION**
Plaintiffs,	:	
	:	
v.	:	**No.: 09-CV-4264**
	:	
ABBOTT LABORATORIES,	:	
Defendant.	:	

MEMORANDUM

SITARSKI, M.J. **January 15, 2016**

Presently before this Court is Relator Amy Bergman's Letter Motion to Renew Her Motion to Determine the Sufficiency of Abbott's Answers and Objections to Relator's First Set of Requests for Admissions, as to Requests for Admission Nos. 31, 37-40, 58-60, and 66-68. (ECF No. 138, *see* ECF No. 102). Defendant has opposed this motion. (*see* ECF Nos. 104, 138). The Honorable C. Darnell Jones, II referred this motion to the undersigned for disposition. (ECF No. 103). I heard oral argument on this motion on October 29, 2015.

As more fully set forth herein, Relator's Motion is denied.

I. BACKGROUND

The facts and posture of this case are well-known to the Parties, so the Court provides only a brief recitation of the details pertinent to this motion. In this *qui tam* action, Relator brings claims under the False Claims Act, 31 U.S.C. § 3729, and similar state statutes. (Mem. 1, ECF No. 63; *see also* Am. Compl. 1-104, ECF No. 18). Relator alleges, *inter alia*, that Defendant illegally marketed its drug TriCor for off-label uses — uses not approved by the United States Food and Drug Administration ("FDA"), thereby causing the submission of false claims to government healthcare systems, including Medicare, Medicaid, TRICARE, and the Federal Employee Health Benefits Program. (Mem. 1; Am. Compl. ¶ 6). Relator asserts

Defendant used a variety of methods to carry out the allegedly illegal marketing scheme, including training its sales representatives on the off-label and medical unnecessary uses that Defendant wanted to promote, instructing sales representatives to promote those uses when making sales calls to physicians, and providing sales aids and materials to its sales representatives that promoted off-label and medically unnecessary uses of TriCor. (Am. Compl. ¶ 15).

In May and June of 2015, Relator filed multiple discovery motions, including a Motion to Determine the Sufficiency of Abbott's Answers and Objections to Relator's First Set of Requests for Admissions. (ECF Nos. 102, 105, 114, 117). Judge Jones referred the motions, as well as all future pre-trial discovery motions, to me for disposition. (ECF Nos. 103, 108). I then ordered the parties to attend an in-person meet and confer on June 30, 2015, to be followed by oral argument on any unresolved discovery motions. (ECF No. 119). The parties informed me that as a result of the in-person meet and confer, they entered into a Joint Discovery Agreement to resolve the outstanding discovery motions. (*See* ECF No. 126). Consequently, I denied the outstanding discovery motions without prejudice, and informed Relator that if necessary, she could file a letter request to renew the motion(s). (ECF No. 125).

On September 11, 2015, Relator filed a letter request to renew her Motion to Determine the Sufficiency of Abbott's Answers and Objections to Relator's First Set of Requests for Admissions, but informed the Court that only the responses to Requests for Admission Nos. 31, 37-40, 58-60, and 66-68 were in dispute. (ECF No. 138). I heard oral argument on the responses to the Requests for Admission at issue on October 29, 2015.

II. LEGAL STANDARD

"It is well established that the scope and conduct of discovery are within the sound discretion of the trial court." *Marroquin-Manriquez v. I.N.S.*, 699 F.2d 129, 134 (3d Cir. 1983).

As long as the non-privileged information is relevant to any party's claim or defense and is proportional to the needs of the case, parties may utilize various discovery tools, even if the requested information would not be admissible at trial. Fed. R. Civ. P. 26(b)(1); *Guinan v. A.I. duPont Hosp. for Children*, No. 08-228, 2008 WL 938874, at *1 (E.D. Pa. Apr. 7, 2008).

A party may serve requests for admission ("RFAs") upon the opposing party concerning "statements or opinions of fact or of the application of law to fact." *Creely v. Genesis Health Ventures, Inc.*, No. 04-0679, 2005 WL 44526, at *2 (E.D. Pa. Jan. 10, 2005) (quoting Fed. R. Civ. P. 36(a)). The purpose of RFAs is to expedite litigation by obtaining simple facts to narrow the issues and acquire information needed to make use of other discovery methods. *Guinan*, 2008 WL 938874, at *1; *Hayes v. Bergus*, No. 2:13-cv-4266, 2015 WL 5666128 (D.N.J. Sept. 24, 2015). "Requests for admissions are not intended for factual discovery that should be done through interrogatories and depositions." *Russo v. Baxter Healthcare Corp.*, 51 F. Supp. 2d 70, 79 (D.R.I. 1999); *see Mueller v. CBS, Inc.*, No. 99-cv-1310, 2001 WL 1781926, at *1 (W.D. Pa. Aug. 24, 2001) (distinguishing RFAs from other discovery methods). Therefore, RFAs should seek to establish facts already known by the requesting party. *Creely*, 2005 WL 44526, at *2; *see Ghazerian v. United States*, No. 89-8900, 1991 WL 30746, at *1 (E.D. Pa. Mar. 5, 1991) (RFAs are "not properly speaking a discovery device, rather it is 'a procedure for obtaining admissions for the record of facts already known' by the seeker.") (quoting 8 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2253 (1970)).

Parties should limit RFAs to simple and concise statements of fact that "can be denied or admitted with an absolute minimum of explanation or qualification." *Anthony v. Cabot Corp.*, No. 06-4419, 2008 WL 2645152, at *1 (E.D. Pa. July 3, 2008) (quoting *United Coal Cos. v. Powell Constr. Co.*, 839 F.2d 958, 968-69 (3d Cir. 1988)). Ideally, an RFA can be answered simply "yes" or "no." *Zen Invs., LLC v. Unbreakable Co.*, No. 06-4424, 2008 WL 4489803, at *1 (E.D. Pa. Oct. 7, 2008) (citing *Johnstone v. Cronlund*, 25 F.R.D. 42, 46 (E.D. Pa. 1960)). "To

compel answers to vague and indefinite questions capable of more than one interpretation and which require an explanation thwarts the purposes of Rule 36(a)." *Id.* Thus, RFAs should not contain "'half a fact' or 'half truths' which require the answering party to qualify responses." *Id.* (internal citation omitted).

If the opposing party objects to the request for admission, the requesting party can seek a judicial determination of the objection's sufficiency. *Guinan*, 2008 WL 938874, at *1 (citing *United States v. Lorenzo*, No. 89-6933, 1990 WL 83388, at *1 (E.D. Pa. June 14, 1990)). "In evaluating the sufficiency of the answers/objections, the court should consider: (1) whether the denial fairly meets the substance of the Request; (2) whether good faith requires that the denial be qualified; and (3) whether any 'qualification' which has been supplied is a good faith qualification." *McCarthy v. Darman*, No. 07-3968, 2008 WL 2468694, at *2 (E.D. Pa. June 17, 2008) (citing *Guinan*, 2008 WL 938874, at *1).

An objection merely stating that the request is "overly broad, burdensome, oppressive, vague or irrelevant is 'not adequate to voice a successful objection.'" *Id.* (quoting *Josephs v. Harris Corp.*, 677 F.2d 985, 992 (E.D. Pa. 1982)). Rather, the objecting party must state specific reasons supporting such grounds. *Id.* Courts should not tolerate objections or denials based upon "hair-splitting distinctions that frustrate the purpose of the Request." *Anthony*, 2008 WL 2645152, at *1. A party may not object merely because of an unwarranted inference created by a RFA taken out of context. *See id.* (citing *McCarthy*, 2008 WL 2468694, at *4); *see also Caruso v. Coleman Co.*, No. 93-6733, 1995 WL 347003, at *1 (E.D. Pa. June 7, 2005) (citing *Diederich v. Dept. of Army*, 132 F.R.D. 614, 619 (S.D.N.Y. 1990)). Instead, the proper response is an admission or denial with sufficient qualification. *Anthony*, 2008 WL 2645152, at *1. However, RFAs calling for the conclusion of one of the ultimate issues of the case are properly objectionable. *McCarthy v. Darman*, No. 07-CV-3958, 2008 WL 2468694, at *1 (E.D. Pa. June 17, 2008) (quoting *First Options of Chicago, Inc. v. Wallenstein*, No. 92–5770, 1996 WL

729816, at *3 (E.D. Pa. Dec. 17, 1996)). "Where issues in dispute are requested to be admitted, a denial is a perfectly reasonable response." *Zen Invs.*, 2008 WL 4489803, at *1 (citing *United Coal Cos. v. Powell Constr. Co.*, 839 F.2d 958, 967-68 (3d Cir. 1988)).

III. DISCUSSION

Relator argues that Defendant's responses to RFA Nos. 31, 37-40, 58-60, and 66-68 are insufficient, and therefore requests that the responses be amended. Defendant argues that it provided substantive admissions or denials responsive to Relator's RFAs. The Court addresses the sufficiency of Defendant's responses to the RFAs below.

A. RFA No. 31

RFA No. 31 requests that Defendant admit it "knew the contents of TriCor's FDA approved labels regarding the effect of TriCor on coronary heart disease morbidity, coronary heart disease mortality and non-cardiovascular mortality." In its response, "[Defendant] admit[ted] that it was aware of the contents of TriCor's FDA labels and denies the remainder of [the RFA]," qualifying the response with an objection that the topic in the RFA is vague and the RFA presumes that the label addresses the topic in the RFA. Relator counters that the RFA is not vague, and a pharmaceutical company should be aware of the contents of its label.

I find that Defendant's response is sufficient. It is unclear which statements in TriCor's multi-paged FDA approved labels Relator is requesting that Defendant admit or deny. (*See* Am. Compl. Ex. 1 2-5, ECF 104-1). Therefore, RFA No. 31 is capable of more than one interpretation, and is not simple or concise. *See Zen Inv.* 2008 WL 4489803, at *1-2 (finding objection arguing the terms were not defined was proper, where the RFA requested plaintiffs to admit the contents of the by-laws of a company). In similar RFAs asking Defendant to admit to the contents of TriCor's FDA approved label, Relator quoted specific language in the label, thereby eliminating any vagueness. (*See* Resp. Ex. 1 15-16, ECF No. 107-1). Thus,

Defendant's qualification was supplied in good faith. Relator is granted leave to serve amended RFAs that quote specific language from TriCor's FDA labels.

B. RFA Nos. 37-40

RFA No. 37 asks Defendant to "admit that [it] submitted to the FDA one or more requests regarding TriCor which sought approval of TriCor for use in combination with a statin." In its response, Defendant objected to the term "submitted to the FDA one or more requests regarding TriCor" as unclear. Defendant then denied the RFA, with the qualification that it assumed that "request" referred to "a New Drug Application seeking a new indication from the FDA." RFA Nos. 38-40 ask Defendant to admit that it "submitted to the FDA one or more proposed indications for fenofibrate which sought approval for the administration of fenofibrate" to treat specific medical conditions. Defendant denied the RFA, with the qualification that it assumed that "proposed indications" referred to "a New Drug Application seeking a new indication from the FDA." Relator argues that Defendant's assumptions in RFA Nos. 37-40 improperly narrowed the requests.

I find that Defendant's responses are sufficient because the terms "submitted to the FDA one or more requests regarding TriCor" and "submitted one or more proposed indications" are vague. Requests that Defendant may have "[s]ubmitted to the FDA . . . regarding TriCor" can encompass any type of "request," from a request for a telephone call to discuss TriCor, to a request for new drug application. Similarly, "proposed indications" encompasses a broad spectrum of activities, including a new drug application, amended application, and supplemental new drug application. Thus, the terms "submitted to the FDA one or more requests regarding TriCor" and "submitted one or more proposed indications" have more than one interpretation, and Defendant's qualifications were supplied in good faith. *See Zen Inv.* 2008 WL 4489803, at *1. Relator is granted leave to serve amended RFAs that identify specific "requests" or "proposed indications" that Defendant may have submitted to the FDA.

C. RFA Nos. 58-60

RFA Nos. 58-60 ask Defendant to admit that it provided its sales and marketing staff with specific reprints for use in marketing TriCor. Defendant qualified its response, admitting that "sales representative received [the specific materials] with instructions for use consistent with the TriCor label and FDA guidelines." Relator contests the qualifying language.

I need not address RFA Nos. 58-60 because Defendant has agreed to amend its responses by removing the qualifying language, "with instructions for use consistent with the TriCor label and FDA guidelines." After such modification, the responses will sufficiently answer the RFAs.

D. RFA Nos. 66-68

RFA Nos. 66-68 ask Defendant to admit that it "provided its sales and marketing staff with one or more non-branded sales aids which discussed or referred to" specific studies related to off-label uses of TriCor. (*See generally* Am. Compl. ¶¶ 55-108). Defendant objected to the terms "non-branded sales aid" and "sales and marketing staff" as undefined terms whose meanings are unclear. Nevertheless, Defendant "admit[ted] that sales representatives received non-promotional materials that 'discussed or referred to' [specific studies] with instructions for use consistent with TriCor's label and FDA guidelines." Relator objects to the response, asserting that terms "non-branded sales aid" and "sales and marketing staff" are both terms of art, specifically arguing that the terms "non-branded sales aid" is used in Defendant's internal documents.

I find that Defendant's responses are sufficient. First, the term "sales and marketing staff" is broad, as it refers to two distinct groups of Defendant's staff — sales staff promotes products to the customers externally, while marketing staff strategizes internally about the promotion and selling of products. Defendant's qualification, distinguishing sales representatives from marketing staff, is therefore a good faith qualification. *See Zen Invs.*, 2008 WL 4489803, at *1.

Second, it is unclear whether the term "non-branded sales aid" is a term of art within the industry or Defendant's company. In support of her motion, Relator provided two internal documents from Defendant, produced during discovery, to demonstrate that the term "non-branded sales aid" is well-defined. However, the use of the term "non-branded sales aid" in ***two*** of Defendant's internal documents does not qualify it as a term of art. It is possible that during the course of discovery, the parties may determine that the term is used consistently within the industry, or within Defendant's company. Based on the current evidence provided, I cannot conclude that the term is well-defined.

Moreover, the definition of "non-branded sales aid" may be an ultimate issue in the case. Relator alleges, *inter alia*, that Defendant illegally marketed TriCor for off-label and medically unnecessary uses, violating the FDA's restrictions on "off-label" marketing. (Mem. 4-5). Therefore, as discussed by the parties during oral argument, the definition of "non-branded sales aid" — whether it constitutes promotional materials or educational materials — may be an issue in dispute. Because of the significance of the definition, Defendant "should be able to explain its position [through other methods of discovery] and not be bullied into an admission it does not want to make." *Tri-State Hosp. Supply Corp., v. United States*, 226 F.R.D. 118, 138 (D.D.C. 2005); *see Zen Invs.*, 2008 WL 4489803, at *1. Further probing into this term should be accomplished through other means of discovery, such as interrogatories and/or depositions. *See Russo*, 51 F. Supp. 2d at 79. Fact discovery is scheduled to continue until January 6, 2017. If, during the course of discovery, the parties determine that the term "non-branded sales aid" is well-defined, then Defendant shall amend its responses to the RFAs as required by the Rules of Civil Procedure. Fed. R. Civ. P. 26(e)(1).

IV. CONCLUSION

For the foregoing reasons, Relator's Letter Motion to Renew her Motion to Determine the Sufficiency of Abbott's Answer and Objections to Relator's First Set of Requests for Admissions, as to Requests for Admission Nos. 31, 37-40, 58-60, and 66-68 is denied. An appropriate Order follows.

BY THE COURT:

/s/ Lynne A. Sitarski
LYNNE A. SITARSKI
UNITED STATES MAGISTRATE JUDGE